CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

September 9, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Comments on Current Good Manufacturing Practices; Docket No. 2004N-0230

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to submit written comments on FDA's review of its Current Good Manufacturing Practices (CGMPs). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition and alcohol issues. CSPI is supported principally by nearly 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding.

The CGMPs, as FDA has stated, "are requirements for protecting foods from conditions that may render the food injurious to health and cause the food product to be adulterated . . . ."[1] However, because they were last revised almost 20 years ago, the CGMPs are more focused on the quality, identity, and composition of foods, rather than on food safety. The CGMPs do have a number of strengths that should be retained during this revision. For example, the section

[1] FDA, FSIS, CDC, *Healthy People 2010 Focus Area Data Progress Review*, Focus Area 10: Food Safety, Challenges, Barriers, Strategies and Opportunities, Section 10-4 (May 11, 2004)

addressing the health of personnel is highly relevant today in order to protect against hazards such as Hepatitis A and Norwalk-like viruses. These provisions should be further strengthened with additional enforcement controls. Daily assessment of employee health, cleanliness, and hand washing is a critical responsibility of management and should be accompanied by multi-lingual training to ensure that individual employees understand the importance of these requirements in protecting themselves and their customers.

Below, we set forth our recommendations for ways in which the CGMPs should be redesigned to better assure food safety.

I. The Definition Section Should Be Updated And Expanded

The definitions section should be substantially revised and enlarged by deleting certain definitions, amending other definitions, and adding new definitions. Among other things, the following changes should be made:

- Redefine "critical control point" to be: "a point, step or procedure in a food process step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level."

- Add a new definition of "critical limit:" - "the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

- Add a new definition for "food safety hazard" - "any biological, chemical, or physical agent in food that may cause food to be unsafe for human consumption."

In addition, definitions should be added for other terms, including Standard Sanitary Operating Procedures, HACCP plan, validation, verification, ready-to-eat foods, and allergens.

II. Strengthen The Language of The CGMPs

The CGMPs are written as regulations and not guidelines. Accordingly, requirements should be stated in mandatory "shall" language and not "should." This would strengthen uniformity between state and federal regulatory agencies, as well as agencies' ability to enforce these requirements.

III. GMPs Should Be Revised to Emphasize Risk-Based Control Point Analysis

The CGMP's are written as general regulations that apply to all foods. They should be redrafted to include risk-based regulations for preventing specific hazards. For all three categories of food contamination – microbial, chemical and physical - GMPs should require HACCP-like procedures for the identification of hazards and interventions to control those hazards. Manufacturing operations should be required not only to manufacture their products "under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food" but to document those controls with appropriate recordkeeping.[2] In addition, the concept that process controls must be verified through a routine sampling program should be integrated wherever relevant throughout the regulation.

To help ensure that preventative controls are fully implemented, we recommend that the following measures should all be required for food manufacturers and processors:

- Training programs for managers and/or workers;
- Testing of incoming raw materials, in-process materials or finished products;
- Written sanitation standard operating procedures;

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[2] 21 C.F.R. § 110.80(b)(2).

- Written records for sanitation between batches;
- Effective recordkeeping to document hazards and control measures;
- Validation of control measures;
- Audit programs; and
- Food label review and control programs.

In addition, the revised CGMPs should provide that food establishments that produce or handle high-risk foods, such as those at risk for *Listeria monocytogenes* (i.e. soft cheese, pasteurized and unpasteurized milk products, seafood products, and prepared salads), be required to meet stiffer standards.[3] Facilities making such products should be required to have written plans addressing *L. monocytogenes* and to test to test their environments and final products for the presence of the pathogen. The CGMPs should also include specific food safety recommendations for other ready-to-eat foods.

IV. Harvest and Transportation Measures Should Be Included

The current GMPs largely exclude harvesting and transportation, and we urge the agency to consider both these areas. The recent Hepatitis A outbreak linked to green onions clearly demonstrates that conditions at the harvesting level can greatly impact the safety of certain food products, especially produce and seafood. Today, consumers expect improved protection for hazards that are foreseeable, even in raw products. In addition, the successful introduction of food safety controls in the USDA organic regulations shows that motivated farmers can

[3] In September 2003, FDA, with the USDA and CDC, published a risk assessment of foodborne *Listeria monocytogenes* in certain categories of ready-to-eat foods. Foods regulation by the FDA, including unpasteurized fluid milk, smoked seafood, and cooked ready-to eat crustaceans were classed as high risk foods for listeriosis. Moderate risk foods include high fat and other dairy products, soft unripened cheese, and pasteurized fluid milk. *See* FDA, USDA, CDC, *Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocygoenes Among Selected Categories of Ready-to-Eat Foods*, Interpretative Summary (Sept. 2003), at p. 12.

successfully control many agricultural inputs, such as manure, that are linked to food poisoning outbreaks. In fact, with implementation of the manure requirements for organic food, these products may surpass traditional varieties in microbial safety. As food safety controls stretch from farm to fork, it makes sense to expand GMPs to include greater controls on the incoming ingredients, including harvesting conditions in the case of foods that received minimal treatment or processing.

While farms and transportation have generally fallen outside of FDA's oversight, FDA could enforce compliance with new GMPs' by means of random checks. Since the agency has only a small staff of compliance officers, FDA may need to join with the Departments of Agriculture and Transportation, together with state and local inspectors, to enforce compliance with GMPs that extend to farmers or transporters.

Additional transportation GMPs should be incorporated into the revised GMPs or considered as a separate document.[4] These should include specific temperature requirements for transportation and storage, restrictions on back hauling to avoid cross-contamination, sanitation requirements, and basic inventory controls. The GMPs should apply to all entities – including both transporters and warehouses – that handle food items in transit between registered processing establishments, as well as between registered establishments and retail establishments.

If handled as a separate regulation, transportation GMPs should include requirements regarding general vehicle maintenance personnel hygiene, cleaning of utensils and food-contact

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[4] The GMP regulation covering transportation and storage requires only "conditions that will protect food against physical, chemical and microbial contamination." 21 C.F.R. § 110.93. In addition, the FDA's Food Code does not itself establish any regulatory requirements addressing transportation and storage conditions for interstate shipments of foods.

surfaces using safe cleaning compounds, and pest control. The use of insecticides and rodenticides should be permitted only under restrictions that protect against contamination of food, food-contact surfaces, and food-packaging materials. In addition, the GMPs should provide that boxes or packages containing food products that are accidently torn open during shipment be promptly condemned and disposed of if there is any risk of contamination.

Safe temperature requirements should be set for transportation of different food categories and vehicles should be encourage to carry a recording thermometer that can accurately measure and record the temperature within the vehicle compartment. Such devices can record the temperature every hour or at another appropriate interval. This would be further strengthened if the FDA Food Code included requirements that food retailers check the temperature of their incoming product.

We also recommend that transportation GMPs address the risk of cross-contamination, both between food and non-food items and between different foods shipped in the same vehicle.[5] To prevent cross-contamination, we urge the Agency to adopt transportation GMPs that include a prohibition against shipment of meat, poultry or seafood in the same vehicle at the same time as any other food or non-food item that may contaminate, or be contaminated by, the meat, poultry, or seafood products.

FDA should also review the problems associated with back hauling, since public health

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[5] A 1994 salmonellosis outbreak affecting 224,000 people was blamed on cross-contamination of pasteurized ice cream transported in tanker trailers that had hauled non-pasteurized liquid eggs. *See* U.S. Department of Transportation, Office of Inspector General, Audit Report, *Review of Departmental Actions Concerning The Sanitary Food Transportation Act of 1990*, Report Number: TR-1998-100 (Mar. 27, 1998), at p. 4. According to the General Accounting Office, this outbreak was estimated to have cost approximately $18.1 million, including $6.9 million for medical care and $11.2 million in time lost from work. *See* GAO, *Food-Processing Security: Voluntary Efforts Are Under Way, but Federal Agencies Cannot Fully Assess Their Implementation*, GAO-03-342 (Feb. 2003), at p. 2.

concerns necessitate some restrictions. These restrictions may take the form of an absolute prohibition against back hauling for some items, or a requirement that vehicles be sanitized with hot water and an effective disinfectant solution between shipments. In determining which restrictions to place on back hauling, we believe that FDA should consider the following factors: (a) the severity of the hazards involved; (b) the likelihood of cross-contamination; and (c) the effectiveness of sanitization measures. We suggest that, at a minimum, vehicles used to transport food products should be prohibited from also hauling hazardous materials, such as asbestos, radioactive materials, trash, or other refuse that is likely to contain microbiological or chemical contaminants.

V. The GMPs Should Include Concepts of Product Traceability

The revised GMP regulations should more formally include the concepts of product traceability (especially important for product recalls) and ensure that the agency has access to production and distribution records. For example, inventory controls that identify the time and place of harvest or processing would greatly aid in product identification in the event of a recall. Additionally they would help ensure that older food products are not mixed in with newer products or otherwise languish for long periods of time in a vehicle or warehouse.

Product traceability and adequate recordkeeping were both mandated in the Bioterrorism Act of 2002, and are included in regulations currently being adopted by the FDA. Whether considering these issues in light of bioterrorism concerns or in order to manage existing food product recall and outbreak situations, ensuring traceability and agency access to distribution records are critical public health protections.

VI. Compliance and Enforcement Mechanisms

The revised GMPs should incorporate enhanced enforcement systems, including progressive enforcement and criteria to rank the significance of violations. Additionally, they should adopt mandatory notification and traceback procedures for contaminated food and a program of comprehensive, periodic audits by qualified personnel free of conflicts of interest. Companies should be required to develop written programs that clearly state management's approach to fulfilling its food safety functions. Structural independence between the quality assurance and production departments of an establishment is essential.[6] For example, it is unacceptable for Quality Control personnel to be hired or fired by a production supervisor.

VII. Allergens

The current GMPs focus on taking "necessary precautions against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances"[7] and, accordingly, do not address food allergens. However, section 204 of the Food Allergen Labeling and Consumer Protection Act of 2004,[8] directs the FDA to report to Congress by February 2006 on: (a) the ways in which foods during manufacturing and processing are "unintentionally contaminated with major food allergens,[9] including contamination caused by the use by manufacturers of the same production line to produce both products for which major food

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[6] This independence is the cornerstone of international audit standards. *See* ISO 9001 § 4.17.

[7] 21 C.F.R. 110.10(b)(9). *See also* 21 C.F.R. 120.7(c)(hazards that must be considered in a Hazard Analysis and Critical Control Plan for juices), 21 C.F.R. 123.6(c)(1)(hazards that must be considered in a Hazard Analysis and Critical Control Plan for fish and fishery products), 21 C.F.R. 123.20 (steps to be taken to destroy microorganisms in raw molluscan shellfish), and 21 C.F.R. 129.35(a)(samples of water to be taken to detect microbiological and radiological contaminants).

[8] Title II of P.L. 108-282.

[9] The law defines major allergens as milk, egg, fish, shellfish, tree nuts, wheat, peanuts, and soybeans.

allergens are intentional ingredients and products for which major food allergens are not intentional ingredients" and (b) "whether good manufacturing practices or other methods can be used to reduce or eliminate cross-contact of foods with the major food allergens."

Based on these findings, the FDA should revise the GMPs to include specific steps to prevent the inadvertent contamination of packaged foods with the major allergens.

Conclusion

Manufacturing processes should be designed to anticipate and address potential foodborne hazards at each stage of production. Revision of the CGMPs presents the FDA with an opportunity to incorporate risk-based concepts into food production. The risks of foodborne illness associated with FDA-regulated products will be minimized to the greatest extent possible by adoption of these principles. In addition, the GMPs should be revised to address inadvertent contamination of package foods with the major allergens.

Respectfully submitted,

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To Whom It May Concern:

Enclosed are comments on FDA's review of its Current Good Manufacturing Practices (CGMPs) by the Center for Science in the Public Interest. CSPI appreciates the opportunity to submit these comments.

Sincerely,

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